510(K) Summary

K081557

SEP 1 0 2008

1. Company Identification

JDDB Manufacturing, Inc.
446 W. 128th Place
Chicago, Illinois
Tel: 816-914-4871-7413
Fax: 773-264-5751

2. Official Correspondent

Jacquin C. Youngblood-Johnson (Ms.)
Post Office Box 277782
Riverdale, Illinois 60827-7782

3. Date of Submission

September 2, 2008

4. Device Trade Name

Portable Supine Patient Support and Cassette Holder

5. Common Name

Scoliosis Supine Cassette Holder

6. Classification

Radiographic film cassette, Class II per CFR 892.1850.

7. Applicable Standard

Voluntary standard to which the Portable Supine Patient Support and Cassette Holder conforms is: ISO 4090:2001

8. Intended Use

The Portable Supine Patient Support and Cassette Holder is a supine support device intended to lay flat on a flat surface to hold and position a radiographic cassette, also to hold and position a patient for radiographic x-ray exposure. I intended for medical use.

9. Description of Device

The Portable Supine Patient Support and Cassette Holder is a portable, non-ionizing radiation device used for scoliosis radiography of the spine. The device consists of a head support, a rectangular cassette holder (94cmx40.5cm), which will hold the cassette, a foot support, and a removable cover top on top of the cassette holder.

10. Substantial Equivalence to Predicate Device

The Portable Supine Patient Support and Cassette Holder is substantially equivalent to Trimax Radiographic Cassette; 510(K) number: K980722.

11. Technical Characteristics

The technical characteristics of the Portable Supine Patient Support and Cassette Holder would be the same as those for the predicate device for the cassette. However, the cover top the patient will be positioned on top of, for the radiograph exposure, is made of carbon fiber material. Singled layer of carbon fiber material (2.76mm) meets the radiotranslucency requirements of 21 CFR Ch.1 J 1020.30 (n) Table 2 (2008) criteria for "Tabletop, movable, without articulated joints" as well as Tabletop, with radiolucent panel having one articulated joint" since it is not greater than 1.7mm Al equivalent. The data also indicates that a single layer does meet the radiotranslucency requirement as "Tabletop, stationary, 'without articulated joints" since it does not exceed 1.2 mm Al equivalent. Data attached for two samples of carbon fiber material. I only made reference to one sample in this writing because of space.

12. Who Will Use Device

Children Hospitals, Regular Hospitals, Rehabilitation Institutions, Hospitals for Crippled Children, Orthopedic Clinics, Chiropractic Offices, and Spine/ Scoliosis Clinics.

K & S Associates, Inc.

Test #: D080314
Test Date 07-Mar-08

ACCREDITED

RADIO-TRANSLUCENCY TEST

Submitted By:	Jacquin Youngblood-Johnson JDDB Manufacturing, Inc. 446 West 128th Place Chicago, IL	P.O. # : 401568 Sample: Vanguard 4"X4" Procedure: GL7	Received: 06-Mar-08 Report # 80579

TEMPERATURE:	19.4 °C
PRESSURE:	745.7 inmHg

This Laboratory is accredited by the American Association for Laboratory Accreditation (A2LA) and the results shown in this report have been determined in accordance with the laboratory's terms of accreditation unless stated otherwise in this report.

The indicated sample materials were received on the above date and were tested for their x-ray attenuation properties under conditions of narrow-beam geometry. The energy of the beam was characterized in narrow beam geometry using filters certified as 99.9% pure and is as follows: 100 kVp, Half-value layer = 2.7 mmAl,minum. The ionization chamber used for the measurements has a well understood spectral response curve.

All readings were normalized to the response of a full beam transmission monitor. The following table lists an item number assigned by K&S, the linear thickness measured at K & S, the fraction of the incident beam that passed through the material sample, the thickness of aluminum which would allow an equal fraction of the same beam to pass through (Al equivalence), and finally the ratio of Al equivalence to the measured linear thickness.

The overall uncertainty of the measurement is 3%. This uncertainty is the combined expanded uncertainty of the measurement with a coverage factor of 2 (95% confidence).

Sample Number	Thickness (mm)	Transmission	Al eq. (mm)	mm Al eq /mm
1	2.76	0.884	0.39	0.142

Log:	PH-11
Page:	28

The above data indicate that a single layer of the above samples meets the radiotranslucency requirement of 21CFR Ch. 1, J, 1020.30(n) Table 2 (2006) criteria for "Tabletop, movable, 'without articulated joints" as well as Tabletop, with radiolucent panel having one articulated joint" since it is not greater than 1.7 mm ' Al equivalent.

The data also indicates that a single layer does meet the radiotranslucency requirement as a '"Tabletop, stationary, 'without articulated joints" since it does not exceed 1.2 mm Al equivalent.

Measurement by: Brad Horn

Title: CALIBRATION TECH

Reviewed by:
Larry G. Bryson, MS, CHP
Associate Director

Title:

K & S Associates, Inc.

Test #: D080614
Test Date 07-Mar-08

ACCREDITED
CALIBRATION CERT #1256.01

RADIO-TRANSLUCENCY TEST

Submitted By:	Jacquin Youngblood-Johnson JDDB Manufacturing, Inc. 446 West 128th Place Chicago, IL	P.O. # : 401658 Sample: JPI 6"X6" Procedure: GL7	Received: 06-Mar-08 Report # 80580

TEMPERATURE:	19.4 °C
PRESSURE:	745.7 mmHg

This Laboratory is accredited by the American Association for Laboratory Accreditation (A2LA) and the results shown in this report have been determined in accordance with the laboratory's terms of accreditation unless stated otherwise in this report.

The indicated sample materials were received on the above date and were tested for their x-ray attenuation properties under conditions of narrow-beam geometry. The energy of the beam was characterized in narrow beam geometry using filters certified as 99.9% pure and is as follows: 100 kVp, half-value layer = 2.7 mmAluminum. The ionization chamber used for the measurements has a well understood spectral response curve.

All readings were normalized to the response of a full beam transmission monitor. The following table lists an item number assigned by K&S, the linear thickness measured at K & S, the fraction of the incident beam that passed through the material sample, the thickness of aluminum which would allow an equal fraction of the same beam to pass through (Al equivalence), and finally, the ratio of Al equivalence to the measured linear thickness.

The overall uncertainty of the measurement 3%. This uncertainty is the combined expanded uncertainty of the measurement with a coverage factor of 2 (95% confidence).

Sample Number	Thickness (mm)	Transmission	Al eq. (mm)	mm Al eq /mm
1	2.63	0.886	0.39	0.147

Log: PH-11
Page: 28

The above data indicate that a single layer of the above samples meets the radiotranslucency requirement of 21CFR Ch. 1, J, 1020.30(n) Table 2 (2006) criteria for "Tabletop, movable, without articulated joints" as well as Tabletop, with radiolucent panel having one articulated joint" since it is not greater than 1.7 mm Al equivalent.

The data also indicates that a single layer does meet the radiotranslucency requirement as a "Tabletop, stationary, without articulated joints" since it does not exceed 1.2 mm Al equivalent.

Measurement by Brad Horn

Title: CALIBRATION TECH

Reviewed by Larry G. Bryson, MS, CHP
Associate Director

Title:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 0 2008

Ms. Jacquin C. Youngblood-Johnson
President
JPI America, Inc.
141 – A Central Avenue
FARMINGDALE NY 11735

Re: K081557
Trade/Device Name: Portable Supine Patient Support and Cassette Holder
Regulation Number: 21 CFR 892.1850
Regulation Name: Radiographic film cassette
Regulatory Class: II
Product Code: IXA
Dated: May 22, 2008
Received: June 3, 2008

Dear Ms. Youngblood-Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K081557

Device Name: Portable Supine Patient Support and Cassette Holder

Indications for Use: Supine support intended to lay flat on a surface to hold and position radiographic cassette, also to hold and position patient for radiographic exposure for medical use.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

(Division Sign-Off) Concurrence of CDRH, Office of Device Evaluation (ODE)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K081557